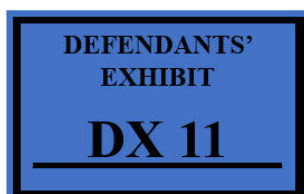


Division Transgender Accommodations Review Committee (DTARC)
Position Statement
Gender Reassignment Surgery
NCDPS-Prisons

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Dr Arthur L Campbell, III, M.D.
Chief Medical Officer, NC Prisons



SUMMARY POSITION STATEMENT:

As with all treatments, including procedures and surgeries provided to offenders, the first consideration is whether the treatment is medically necessary. This consideration is precisely the same as that utilized by every managed care system and health insurance agency in the Country.

After extensive and objective review and analysis of hundreds of studies and other publications, it has been determined that gender reassignment surgery (GRS), as a treatment for gender dysphoria, is not medically necessary.

When GRS is considered with and compared to other procedures and surgeries which are broadly considered medically necessary, GRS procedures fail to satisfy the criteria and characteristics evidenced by those broadly accepted procedures. Specifically, there are concerns that the risk, as defined by failure of the procedure to correct the underlying problem or the need for subsequent reversal of the procedure outweigh any potential benefit of the procedure. GRS simply does not represent an objective "standard of care" and there are grave concerns with significant conflict of interest and the lack of evidence-based, peer-reviewed criteria utilized in developing criteria.

ANALYSIS/ DISCUSSION

There continue to be variable, and at times discrepant definitions of “medical necessity” between medical professionals, insurance providers, legislators, legal authorities, and activists. Across the country, the Courts continue to be somewhat inconsistent in their interpretations of what constitutes “medical necessity”. These discrepancies become even more complex in the context of medical care for the prison population.

Broadly speaking, at the most basic level, a medically necessary procedure is one which is reasonable and necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain. More specifically, there are fairly standard characteristics which most in the medical community would agree either constitute or are associated with a “medically necessary” treatment or procedure, and in the context of gender reassignment surgery (GRS), these characteristics can be applied to reach a determination.

Some prominent characteristics of “medically necessary” procedures include:

- The risk to the patient of not performing the surgery exceed the potential risks of the surgery itself (includes intraoperative, postoperative and long term risks).
- The procedure has been determined to constitute “standard of care”, which leads to the following:
 - Overwhelming majority of individuals with the condition undergo the procedure
 - Majority of health insurance carriers provide coverage for the procedure, particularly when the procedure is not costlier than an alternative service or sequence of treatments that are at least as likely to produce equivalent therapeutic results.
- Treatment recommendations are developed through evidence-based medicine/ practice and are modified based on findings from continuous future studies.

When gender reassignment surgery is considered utilizing the general principles outlined above, it becomes apparent that the procedure(s) are indeed not “medically necessary”. What follows is a summary analysis and explanation.

- **For medically necessary procedures, the risk to the patient of not performing the surgery exceeds the potential risks of the surgery itself.**

From the definition above, it follows that for a "medically necessary" procedure, the consensus among the medical community would be that not undertaking the procedure (surgery) will of course fail to alleviate the symptoms associated with the condition, but most importantly, could also result in one/ more of the following: (1) Death, (2) Severe disability, or (3) Significant worsening of the condition. A procedure which is unlikely to improve symptoms, carries with it increased risk of worsening symptoms, or those that disproportionately jeopardize a patient's well-being would not be considered "medically necessary". In fact, they would instead likely not be recommended at all.

In the case of GRS, it is far from consensus among the medical community that individuals with gender dysphoria who do not undergo the procedure(s) are at increased risk of any of the sequelae outlined above. In fact, there are studies which cause great concern that a not insignificant portion of individuals who undergo the procedure(s) not only fail to improve, but in many cases, experience worse symptoms with quite concerning consequences.

One example: The largest and longest term study looking at quality of life after GCS, conducted in Sweden with 324 individuals over 30 years (1973-2003), actually demonstrated a 20-fold increase in suicides and 2.8 times greater rate of psychiatric hospitalization. Individuals also had a 2-2.5 times greater rate of neoplasm and cardiovascular disease. Importantly, many of these quite concerning outcomes did not occur until 10 years or more after surgery. [1]

Studies demonstrating findings such as those above are not isolated. Another study in 2017, incidentally sponsored by a group that was clearly pro-transition, found that "suicide attempts were lower before transition than over most other periods". For example, the study found that suicidal ideation was 50.6% after transition compared with a 36.1% rate before transition. [2]

Another important consideration in any surgical treatment is outcomes, including analysis of the need for further surgeries, etc. There is a growing body of research into what seems to be an increasing number of transgender individuals who at some point "de-transition", the act of stopping or reversing gender transition, often going back to living as their sex assigned at birth.

This phenomenon of de-transition is critically important in considering treatment options for patients, particularly when treatment involves either irreversible or incredibly difficult/ poor outcomes, such as surgeries.

A study published in the Archives of Sexual behavior in October 2021 found a 24% rate of de-transition. This study uncovered some interesting, and frankly concerning statistics. For example, 60% of those who de-transitioned did so at least partly because they had become more comfortable with their natal(birth) sex. A quite significant amount (49%) did so as a result of concerns about the potential medical complications from transitioning. Perhaps most

significantly, 55% expressed concerns that they had “not received adequate evaluations from a doctor or mental health professional before starting transition”. [3]

Further analysis of this data and other studies demonstrated that of those who de-transitioned, 38% did so because transitioning had failed to resolve their psychological issues, so they concluded that “gender dysphoria wasn’t the cause”; another 23% did so because they came to understand that they had in fact been struggling with sexual orientation issues rather than gender dysphoria. [4]

A large sample, peer-reviewed study conducted in 2021 found that 70% of those who de-transitioned did so after they realized their gender dysphoria was “related to other issues” and 50% did so because transition had failed to alleviate their dysphoria. Interestingly, 43% endorsed a “change in political views” as a reason for de-transition. Importantly, 43% of those who de-transitioned had previously undergone GCS. [5]

Another more recent study (Oct 2021) found that among individuals who de-transitioned, 70% did so due to being dissatisfied with their decision to transition. 61% of those who de-transitioned had returned to their identifying with their birth sex, 14% identified as non-binary, and 8% identified as transgender. The study goes on to emphasize the need for “alternative, non-invasive approaches for gender dysphoria management in young people”. [6]

Findings such as these raise serious concerns and tip the “risk-benefit” analysis away from the support for surgery among objective medical observers, thereby refuting its “medical necessity”.

- **"Medically necessary" procedures are by definition considered to constitute "standard of care".**

If a procedure (surgery in this case) were the "standard of care", there would be a single, or at most a discrete subset of procedures which have been determined by the medical community to be most appropriate to treat the condition.

- ***There are specific criteria which indicate not only the "qualification" for surgery, but also the specific procedure or approach would be best***
- ***There are specific criteria which determine relative or absolute contraindications to surgery***
- ***Based on these standards, the overwhelming expectation would be that (excluding patients who decline surgery against medical advice), that virtually every patient with this condition (and without contraindications) would indeed be provided the procedure.***
- ***Majority of health insurance carriers provide coverage for the procedure, particularly when the procedure is not costlier than an alternative service or sequence of treatments that are at least as likely to produce equivalent therapeutic results.***

When evaluating and researching these factors in the context of GRS, it becomes readily apparent that GRS indeed does not satisfy the requirements necessary for it to be considered "standard of care".

The justification used by those who advocate for surgeries is that they are "necessary" in order to alleviate the "dysphoria" associated with the condition. However, unlike other "medically necessary" surgeries, where there is single or at most a very discrete set of established procedures, in the case of GRS, there is a wide spectrum of continually expanding surgical options designed to treat gender dysphoria.

While not all inclusive, these potential surgical options include (not all inclusive) mastectomy, mammoplasty, orchiectomy, penectomy, metoidioplasty, scrotoplasty, vulvoplasty, vaginoplasty, phalloplasty, voice feminization surgery (anterior glottal web formation; cricothyroid approximation; laser reduction glottoplasty), chondrolaryngoplasty, facial feminization/ masculinization surgery, hip augmentation/ enhancement, gluteal augmentation/ reduction, body contouring and fat transfer, and others.

What this list makes very evident is that there is clearly no established specific (or even series of surgeries) which is the "standard" in the treatment of gender dysphoria. Instead, clinicians and advocates involved in the care of patients with gender dysphoria believe that the extent, type and number of surgeries an individual "needs" ("upper" and/ or "lower") are quite literally determined by what makes the patient feel "complete" (or what they "choose"). Unlike pre-operative evaluations for other surgeries (such as a CT scan, MRI, biopsy, etc), in the case of gender dysphoria, there are no objective studies of any kind that can be performed to either determine indications for surgery or to develop specific surgical recommendations; these

determinations are purely subjective on the part of the individual. These facts alone make it clear that none of these surgeries can in any way be considered "necessary".

Over time, for most every surgical procedure, criteria and pre-operative evaluations are continually refined in order to ensure the procedures are offered only to those patients who are most likely to benefit from the procedure. Data is collected continuously and that data helps to not only identify the best candidates for a particular surgery, but also to determine those who are not likely to benefit, and most importantly, those who have risk factors which would contraindicate the surgery.

In the case of GRS, the opposite is true. Treatment advocacy groups continue to significantly relax criteria to the point where it is simply a matter of the individual "asking" for the procedure(s). In fact, their approach to individuals with gender dysphoria has just recently been updated to an "informed consent model"/ "affirmation only" model, which "seeks to better acknowledge and support patient's right of, and their capability for, personal autonomy in choosing care options without the requirement of external evaluations or therapy by mental health professionals" [7]

Another important consideration is the fact that for traditional "medically necessary" surgeries, the overwhelming majority of patients with the condition (unless there are specific contraindications or the patient declines), will indeed end up undergoing the procedure. This too is not the case at all with GRS. In fact, only 25-35% of individuals with gender dysphoria ever undergo any GRS. [8]. This further substantiates the case that GRS for the treatment of gender dysphoria is indeed not "medically necessary", as the vast majority of individuals never undergo these procedures. That is not the case at any truly "medically necessary" surgeries.

Another factor with "medically necessary" procedures (again, which equates to being the "standard of care") is that due to these procedures being established as the "standard of care", the majority of health insurance carriers provide coverage for the procedure, particularly when the procedure is not costlier than an alternative service or sequence of treatments that are at least as likely to produce equivalent therapeutic results. This too is not true when evaluating the current state of health insurance coverage for GCS.

At the federal level, CMS (Centers for Medicare and Medicaid), after an exhaustive review of hundreds of studies in 2016, concluded that the procedures would not be mandated as part of Medicare plans due to the conclusion that there is a "lack of evidence that the procedures benefits patients". More specifically, the Decision Memo stated the following: "Based on a thorough review of the clinical evidence available at this time, there is not enough evidence to determine whether gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria", and went on to conclude that there is no evidence of "clinically significant changes" after GRS. [9]

Similarly, at the State level, while there are expected variations, 64% (32) of States' Medicaid Programs also do not provide GRS coverage. [10] Further, most State Employees' Health Plans (including North Carolina) do not provide coverage for GRS.

When specifically considering GRS in prisons, it is important to note that there have been no Federal inmates who have received GRS and only two states to date have provided for the procedure, both of which were very discrete circumstances in court settlements. Were GRS indeed “medically necessary”, not providing the procedure would bolster court cases regarding the 8th Amendment to the US Constitution. However, this has not been the case. Recent court rulings on this have been inconsistent to say the least. In fact, cases in both the First and Fifth Circuit Courts of Appeal have concluded that the State prison systems did not violate inmate’s rights (did not inflict “cruel and unusual punishment”) by declining provision of GRS for inmates.

More specifically, in the Fifth Circuit Court of Appeals case (March 2019; Gibson v Collier), in its findings, the Court confirmed that *“it is indisputable that the necessity and efficacy of sex reassignment surgery is a matter of significant disagreement within the medical community. As the First Circuit has noted—and counsel here does not dispute—respected medical experts fiercely question whether sex reassignment surgery, rather than counseling and hormone therapy, is the best treatment for gender dysphoria.”*

Further, the Court provided the following explanation:

“Under established precedent, it can be cruel and unusual punishment to deny essential medical care to an inmate. But that does not mean prisons must provide whatever care an inmate wants. Rather, the Eighth Amendment “proscribes only medical care so unconscionable as to fall below society’s minimum standards of decency.” Interestingly, the Court went on to point out that something (in this case, GRS) cannot be “unusual” if doing so is not the “usual” treatment, which is clearly the case in the context of GRS in either prisons or across the country as a whole. [11]

None of these would be the case were GRS indeed the “standard of care” and the procedures were “medically necessary”, which further bolsters the case that these procedures are indeed not medically necessary.

- **Treatment recommendations are developed through evidence-based medicine/ practice and are modified based on findings from continuous future studies.**

Surgical procedures are determined using evidence-based, peer-reviewed medical studies which are free of bias or conflict of interest, leading to near consensus among the medical community as to not only the necessity of the treatment/ procedure, but further, the preferred treatment.

- *Critically important is that these studies continually evaluate (and modify based on the data obtained) the pre-operative, intra-operative, post-operative, and long term approaches and prognosis associated with the procedure.*

This factor associated with evaluating medical necessity for any procedure is critical in order to ensure the best care for our patients, and in the case of GRS, is perhaps one of the most concerning factors. Unfortunately, in the case of GRS in the treatment of gender dysphoria, this level of scrutiny is simply not present. Most notably, the entity most often referred to for guidance regarding treatment of gender dysphoria, namely WPATH (World Professional Association for Transgender Health), simply does not utilize these criteria in developing their "standards of care". This realization has led to individuals/groups, who are supportive of treatments for gender dysphoria but who lack confidence in WPATH, establishing other organizations in order to ensure the level of scrutiny needed in undertaking these procedures.

For example, the Society for Evidence-Based Gender Medicine (SEGM) has recently been established by a physician in Oregon who has grown increasingly concerned with the lack of objectivity displayed by WPATH, stating that the organization "remains captured by activists". "We need a serious organization to take a sober look at the evidence and that is why we have established the Society for Evidence-Based Gender Medicine [SEGM]," she noted. "This is what we do — we are looking at all of the evidence. "She specifically recommends the WPATH SOC not be "the new gold standard going forward, primarily because it is not evidence-based". Instead, she points out that "WPATH utilizes the 'Delphi consensus process' to determine their recommendations, but this process is designed for use with a panel of experts when evidence is lacking". Instead of a panel of experts, she and an increasing number of other physicians across the country view WPATH as a "panel of activists" instead of a panel of experts. [12]

Medically necessary treatments must be based on standards of practice, must be evidence-based, peer-reviewed and without bias or conflict of interest among the researchers or agency providing the recommendations, and there is almost always consensus among the medical community as to not only the necessity of the treatment/ procedure, but further, the preferred treatment. These factors establish standard of care, and physicians are derelict in their duties when they stray from these critical considerations.

Unfortunately, the literature often relied upon is fraught with study design problems, including convenience sampling, lack of controls, cross-sectional design, small sample sizes, short study lengths, and enormously high drop-out rates among participants. Very few studies on transition escape these issues. For example, a 2018 systematic review of quality-of-life studies of transitioned adults rated only two out of twenty-nine studies as high-quality. [13]

WPATH remains under increasing scrutiny and continues to be mired in controversy for the very reasons cited above, calling into question its objectivity and the very real concern that it is not the typical professional organization that develops reliable clinical practice guidelines. WPATH is considered by many to instead be a hybrid professional and activist organization, where activists have become voting members, and even move on to lead the organization. In fact, it is argued by many that WPATH is "activist-led" rather than "evidence-led", and therefore are not a reliable agency in medical decision making for our patients.

Conflicts of interest among the organization are also of significant concern. The overwhelming majority of WPATH Committee members either receive income based on recommendations in the guidelines, work at clinics or universities who receive funds from advocacy groups, foundations, or pharmaceutical companies who heavily favor a certain treatment paradigm, or have received grants and published papers or research in transgender care. [14]

The majority of the members of the WPATH Committee are from the U.S., and six of them have affiliations with the same university—the University of Minnesota Program in Sexuality, which is primarily funded by a transgender advocacy organization (Tawani Foundation). In fact, the current chairman of WPATH has his very position at the University of Minnesota funded by Jennifer Pritzer, a trans person and head of Tawani. In fact, there are press releases of Eli Coleman in 2017 thanking Jennifer Pritzer profusely for a generous donation, which adds up to 6.5 million dollars that Tawani has given to the university. Tawani also funded WPATH SOC development. Another advocacy group, Gender Identity Research and Education Society (GIREs) funded the translation of the SOC into various languages. [14]

As if the factors above were not concerning enough, the situation becomes more concerning when we consider another source we as practitioners use to develop treatment plans for our patients, namely specialty societies. In the case of WPATH, three of the same committee members for the WPATH Guidelines also served on the Endocrine Society guideline committee, which raises intellectual conflict of interest concerns, as recommendations based on faulty conclusions in the WPATH guidelines could potentially have been duplicated in the Endocrine Society guidelines.

This concern is supported by the fact that ECRI (Emergency Care Research Institute), the DHHS-appointed Agency for Healthcare Research and Quality (AHRQ) for the National Guideline Clearinghouse (NGC), has failed to provide Trust Ratings for either WPATH or the Endocrine Society guidelines for the treatment of gender dysphoria. The reason for this lack of inclusion was because "only a few of the recommendations were supported by the systematic review; the majority were not", and that the agencies "did not use a systematic review process" in developing their guidelines. [14]

When, as clinicians we encounter concerns related to objectivity or conflict of interest, for instance, a study recommending a particular pharmacologic treatment or prosthetic device wherein the study was funded by the pharmaceutical company or prosthetic manufacturer, we are then obligated to expand our research and consider other studies. To do otherwise as medical professionals would be negligent; we simply cannot rely solely on a single organization with these concerns at the forefront in making decisions for our patients. This is precisely the

case here, where there is significant concern for objectivity and conflict of interest among WPATH, as well as the US Endocrine Society.

When further research is conducted, as we have done in this case, it becomes even more apparent why there is indeed not consensus among the medical community in the treatment of gender dysphoria, and particularly GCS.

In summary, based on the extensive and objective review of hundreds of studies and other publications, it is quite clear that gender reassignment surgery as a course of treatment for gender dysphoria is indeed not a medical necessity. When GRS is considered with and compared to other procedures and surgeries which are broadly considered medically necessary, the procedures fail to satisfy the criteria and characteristics evidenced by those procedures. Specifically, there are concerns that the risk, as defined by failure of the procedure to correct the underlying problem or the need for subsequent reversal of the procedure outweigh the potential benefit of the procedure. GRS simply does not represent an objective "standard of care" and there are grave concerns with significant conflict of interest and the lack of evidence-based, peer-reviewed criteria utilized in developing criteria.

Accordingly, to support these procedures given all these concerns would be in conflict with the most critical imperative in medicine, "*Primum non nocere*" (First, do no harm"). This imperative is the underpinning of the oath all physicians take. In order to ensure the most appropriate, effective, and safest care to patients, clinicians must exercise due diligence in evaluating all available information in formulating recommendations to patients. The evidence regarding GCS does not provide sufficient confidence that the procedures should be undertaken without concern for having violated that oath.

CITATIONS

- [1] Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden (plos.org)
- [2] Varied Reports of Adult Transgender Suicidality: Synthesizing and Describing the Peer-Reviewed and Gray Literature | Transgender Health (liebertpub.com)
- [3] Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition Who Subsequently Detransitioned: A Survey of 100 Detransitioners | SpringerLink
- [4] Factors Leading to "Detransition" Among Transgender and Gender Diverse People in the United States: A Mixed-Methods Analysis - PMC (nih.gov)
- [5] Why Some Transpersons Decide to Detransition | Psychology Today
- [6] Full article: Detransition-Related Needs and Support: A Cross-Sectional Online Survey (tandfonline.com)
- [7] Demographic and temporal trends in transgender identities and gender confirming surgery (nih.gov)
- [8] Growing Focus on Detransition | SEGM
- [9] Informed Consent in the Medical Care of Transgender and Gender-Nonconforming Patients | Journal of Ethics | American Medical Association (ama-assn.org)
- [10] NCA - Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N) - Proposed Decision Memo (cms.gov)
- [11] Issue brief: Health insurance coverage for gender-affirming care of transgender patients (ama-assn.org)
- [12] Gibson v. Collier, No. 16-51148 (5th Cir. 2019) :: Justia
- [13] WPATH Draft on Gender Dysphoria 'Skewed and Misses Urgent Issues' (medscape.com)
- [14] Quality of life of treatment-seeking transgender adults: A systematic review and meta-analysis | SpringerLink
- [15] Bias, not evidence dominates WPATH transgender standard of care - CANADIAN GENDER REPORT